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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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08/477,147

06/07/1995

PHILIP O. LIVINGSTON

43016-D/JPW/

5687

7590

02/22/2005

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EXAMINER

HOLLERAN, ANNE L

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 02/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

08/477,147

Applicant(s)

LIVINGSTON ET AL.

Examiner

Anne Holleran

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 123 and 130-145 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 123 and 130-145 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
- Paper No(s)/Mail Date \_\_\_\_\_.

- 4) ☒ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. 2/16/2005
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

1. The amendment October 21, 2004 is acknowledged.
2. Claims 123, and 130-145 are pending and examined on the merits.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Claim Rejections Withdrawn:***

4. The rejection of claims 123, 124, 130-145 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in view of the amendment to the claims.
5. The rejection of claims 123, 124, and 130-145 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendment to the claims and specification and applicants' remarks on the record with regard to QS-21.
6. The rejection of claims 123, 124, 134, 135 and 137-145 under 35 U.S.C. 103(a) as being unpatentable over Wiegand (U.S. Patent 5,599,914; issued Feb. 4, 1997; filed Nov. 24, 1989) in view of Jennings (U.S. Patent 4,356,170; issued 1982), in view of Neurath (U.S. Patent 4,591,552; issued 5/27/1986), in view of Ratcliff (U.S. Patent 5,344,870; issued 9/6/1994;

Art Unit: 1642

effective filing 11/30/1988), in view of Patrick (U.S. Patent 4,652,629; issued 3/24/1987), in view of Blincko (U.S. Patent 5,256,409; issued 10/26/1993; effective filing 1/25/1991), in view of Marciani (*supra*), in view of Tsuchida (Journal of the National Cancer Institute, 78: 45-54, 1987), in view of Ritter (1991 of record) and further in view of Livingston (Proc. Natl. Acad. Sci. USA, 84: 2911-2915, 1987) is withdrawn in view of applicants' persuasive arguments that one of ordinary skill in the art would not have had a reasonable expectation of success in using QS-21 to increase the immunogenicity of a ganglioside conjugate in view of the teachings of Marciani, which are directed to using QS-21 to increase the immunogenicity of a viral peptide antigen.

7. The rejection of claims 135 and 136 under 35 U.S.C. 103(a) as being unpatentable over Wiegand (U.S. Patent 5,599,914; issued Feb. 4, 1997; filed Nov. 24, 1989) in view of Jennings (U.S. Patent 4,356,170; issued 1982), in view of Neurath (U.S. Patent 4,591,552; issued 5/27/1986), in view of Ratcliff (U.S. Patent 5,344,870; issued 9/6/1994; effective filing 11/30/1988), in view of Patrick (U.S. Patent 4,652,629; issued 3/24/1987), in view of Blincko (U.S. Patent 5,256,409; issued 10/26/1993; effective filing 1/25/1991), in view of Marciani (*supra*), in view of Tsuchida (Journal of the National Cancer Institute, 78: 45-54, 1987), in view of Ritter (1991 of record) in view of Livingston (Proc. Natl. Acad. Sci. USA, 84: 2911-2915, 1987) and further in view of Diatlovitskaia et al. (Biokhimiia, 56(3): 560-564, 1991, Mar.; Abstract only) is withdrawn in view of applicants' persuasive arguments that one of ordinary skill in the art would not have had a reasonable expectation of success in using QS-21 to increase

Art Unit: 1642

the immunogenicity of a ganglioside conjugate in view of the teachings of Marciani, which are directed to using QS-21 to increase the immunogenicity of a viral peptide antigen.

***Claim Rejections Maintained:***

8. The provisional rejection of claims 123, 124 and 130-145 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending Application No. 08/196,154 is maintained for the reasons of record. Applicants' remarks concerning their intent to file a terminal disclaimer are acknowledged.

***New Grounds of Rejection:***

9. Claims 123 and 130-145 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 123, 132, 134 and 135 are indefinite because they refer to a "ganglioside:Keyhole Limpet Hemocyanin" molar ratio as a characteristic of the conjugate, when the conjugate comprises a "ganglioside derivative" as described in the claims. This rejection would be obviated by amending claims 123, 132, 134 and 135 to recite: "ganglioside derivative:Keyhole Limpet Hemocyanin molar ratio..." and if the phrase "the derivative of which is present in the conjugate", were removed, which phrase appears at the end of the claim.

Art Unit: 1642

***Conclusion***

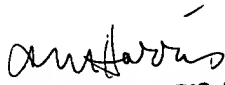
No claim is allowed. Claims 123 and 130-145 are free of the art. Upon receipt of the terminal disclaimer and amendment of claims 123, 132, 134 and 135, as suggested above, the claims will be allowed.

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (571) 272-0833. Examiner Holleran can normally be reached Monday through Friday, 9:30 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at (571) 272-0787.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 571-1600.

Anne L. Holleran  
Patent Examiner  
February 17, 2005

  
**ALANA M. HARRIS, PH.D.**  
**PRIMARY EXAMINER**